Appendix A

A.1 Department Wide Initiatives

CFR Cite	Reference	Agency	Purpose	Impact
Updating regulations in recognitions of changing technology				
45 CFR §§1355.50 – 56	Statewide Automated Child Welfare System (SACWIS)	ACF/ACYF/CB	Grant greater flexibility to States to implement automation that supports their business model; Reduce costs; Reflect changing technology advances; Enable Tribes to implement SACWIS-like systems	Increased flexibility at reduced costs for title IV-E agencies
45 CFR §1351.17	How is application made for a Runaway and Homeless Youth Program grant?	ACF/ACYF/FYSB	Update outdated procedures for obtaining announcements and submitting applications.	Reduce confusion and streamline application process using automation
45 CFR Parts 301, 302, 303, 304, 305, 307	Efficiency in child support	ACF/OCSE	OCSE is drafting an NPRM which improves document management, by allowing states to submit and accept information electronically, maintain electronic records, and accept electronic signatures.	OCSE, States, and others will have the flexibility to use cost-saving and efficient technologies, such as email or electronic document storage, wherever possible.
42 CFR Part 67	Health Services Research, Evaluation, Demonstration, and Dissemination Projects; Peer Review of Grants and Contracts	AHRQ	Update of Regulations [Federal Register Volume 62, Number 52 (Tuesday, March 18, 1997)], pages 12906 - 12914	Minimal impact; primary purpose is to revise and update this AHRQ Peer Review Regulation
42 CFR 37	Specifications for Medical Examinations of Underground Coal Miners (NPRM, RIN 0920-AA21)	CDC	Modification will allow the use of digital radiography in medical screening of coal miners for coal workers' pneumoconiosis. Current regulations require the use of film radiography which is being phased out of use at medical facilities in the U.S.	Use of current technology will increase accessibility of services to coal miners. Also anticipate decreased cost for mine operators to obtain modern digital chest images instead of outdated chest x-rays
21 CFR 310 21 CFR 414 21 CFR 600	Postmarketing Safety Reports for Human Drugs and Biological Products; Electronic Submission Requirements (e-SADR)	FDA/CDER	FDA is revising its regulations to allow mandatory safety reports to be transmitted electronically.	Would allow FDA to collect and analyze safety reports more quickly and to identify emerging problems faster and disseminate information.
21 CFR 314 21 CFR 601	Electronic Submission of Clinical Study Data (e-CSD)	FDA/CDER	FDA is revising its regulations to require submission of data in drug applications in electronic format that FDA can process, review and archive.	Use of modern technology would increase efficiency and allow for more comprehensive data review.
21 CFR 201	Electronic Distribution of Prescribing Information for Human Prescription Drugs and Biological Products (e-Labeling)	FDA/OP	This rule would require electronic “package inserts “for human drug and biological products.	Up-to-date prescribing information for healthcare professionals.
21 CFR 207	Electronic Registration and Listing for Drugs (e-DRLS)	FDA-CDER	Would convert the registration and listing process to a paperless system, while maintaining an avenue for companies that do not have access to the web.	Would allow for the utilization of latest technology in the collection of information and improve FDA’s ability to inspect manufacturing establishments.

21 CFR 807	Electronic Registration and Listing for medical devices	FDA/CDRH	Would convert the registration and listing process to a paperless system, while maintain an avenue for companies that do not have access to the web.	Would allow for the utilization of latest technology in the collection of information.
42 CFR Part 485	Telemedicine Final Rule	CMS	Would allow practitioners in one Medicare participating hospital to provide consultation and services to a patient in another Medicare participating hospital without requiring certification in the second hospital.	Published May 11, 2011. Expected to increase access to health care providers and reduce costs. CMS estimates $13.6 million in net annual savings to hospitals from this initiative.
21 CFR 4	Current Good Manufacturing Practices (CGMPs) for Combination Products	FDA/OC	Would clarify and codify CGMPs requirements for products that are combinations of drug, device and/or biological products.	Would provide regulatory clarity for manufacturers of combination products.
21 CFR 4	Postmarketing Safety Reporting for Combination Products	FDA/OC	Would clarify that a combination product is subject to the reporting requirements associated with the type of marketing application under which the product was approved.	Would provide regulatory clarity for manufacturers of combination products.
Review reporting and recordkeeping requirements to reduce burden				
45 CFR Parts 1385-1388	Requirements applicable to the developmental disabilities program	ACF/ADD	The original NPRM from June 2008 (to establish long overdue regulations for full reauthorization of the DD Act of 2000) received negative comments. ADD plans to rewrite the package to reduce administrative burden; to reflect improvements in data collection, performance measurement and reporting; and to improve consistency with the statute.	Additional flexibility and reduced administrative burden. Reflect improvements in data collection, performance measurement and reporting. Improved consistency with the statute.
42 CFR 34	Medical Examination of Aliens	CDC	NPRM will propose streamlining regulations, updating vaccination requirements and definition changes for drug abuse and drug addiction, revise the scope of the medical examination, and update the list of a communicable disease of public health significance.	Rule reduces the burden and streamlines the immigration process for both the physicians conducting the medical examinations and the U.S. communities receiving immigrants and refugees.
42 CFR 71.53 71.53	Control of Communicable Diseases: Foreign and Possessions Regulations; Nonhuman Primates (NPRM, RIN 0920-AA23).	CDC	NPRM proposes to modify and streamline existing regulations and guidance to reduce administrative burdens for importers of NHPs.	NPRM proposes to reduce the frequency at which importers of nonhuman primates are required to renew their registrations, and to eliminate quarantine costs for zoo-to-zoo and laboratory-to-laboratory facilities that maintain detailed records.
42 CFR Part 412	Inpatient Prospective Payment System Final Rule	CMS	Currently hospitals must provide actuarial determinations for pension costs and Medicare contractors must review those actuarial reports. Revised reporting could reduce burden by removing the need for an actuarial determination.	Published August 1, 2011. Expected to provide flexibility to reduce burdens and costs.

45 CFR 164.512	Disclosures of Student Immunization Records to Schools under the HIPAA Privacy Rule	OCR	Better facilitate the disclosure of student immunization records to schools in states that have school entry laws	Will facilitate these public health disclosures, reduce burden on parents and health care providers, and help avoid delays in children beginning school
45 CFR 164.528	HIPAA Privacy Rule Accounting of Disclosures Requirements	OCR	Improve the workability of current disclosure requirements and better balance the burden to regulated entities with the benefit to individuals	Will provide the individual with information about those disclosures that are most likely to have an impact on the individual's legal and personal interests, while reducing administrative burden on regulated entities
45 CFR 164.520	HIPAA Privacy Rule Requirements on Health Plans to Re-Distribute to Individuals Their Notices of Privacy Practices When Material Changes are Made	OCR	This rule will propose changes to reduce administrative burdens on health plans while still ensuring individuals are notified of material changes to privacy practices.	OCR estimates that this rule will achieve a one-time net savings of $120 million with an associated reduction of 2 million burden hours. Savings are expected to accrue to both public and private health plans within 60 days of the compliance date of the regulation.
Reviewing regulations to "clean up" or eliminate outdated provisions.				
45 CFR Part 1370	Family Violence Prevention and Services Programs	ACF/ACYF/FYSB	Rescind the requirement to publish quarterly funding opportunity announcements in the Federal Register and revise regulations to bring them into conformity with the reauthorized Family Violence Prevention and Services Act	Clarity of programmatic operating procedures
45 CFR § 400.11(c)	Award of Grants to States	ACF/ORR	Delete reference to financial status reports being required quarterly for Social Services grants; Add language to require annual reporting for Social Services grants with the flexibility for ORR to request financial status reports more frequently in accordance with Part 92.	Reduces burden on states by decreasing frequency of reporting unless a specific need surfaces.
42CFR8	Opioid Treatment Facilities	SAMHSA	Review requirements that methadone clinics are to follow and credentialing agencies are to follow in credentialing such programs.	Provide more flexibility for providers in prescribing and dispensing buprenorphine for opioid addiction. Such flexibility will expand the number of patients receiving this form of treatment and potentially reduce costs associated with drug related crime because more patients are receiving treatment.

A.2 Cross-cutting Agency Efforts within HHS

CFR Cite	Reference	Agency	Purpose	Impact
ACF-SAMSHA efforts to increase flexibility and reduce burdens on states				
45 CFR Parts 301, 302, 303, 304, 305, 307	Efficiency in child support	ACF/OCSE	OCSE is drafting an NPRM which improves document management, by allowing states to submit and accept information electronically, maintain electronic records, and accept electronic signatures.	OCSE, States, and others will have the flexibility to use cost-saving and efficient technologies, such as email or electronic document storage, wherever possible.
45 CFR Part 302	Efficiency in child support	ACF/OCSE	OCSE is drafting an NPRM which increases statutory state law exemption approval periods from three to five years	Provides relief to states by decreasing the frequency with which states have to request an extension of an approved state law exemption.
45 CFR Part 303	Efficiency in child support	ACF/OCSE	OCSE is drafting an NPRM which updates case closure criteria to increase state flexibility and facilitate effective case transfer between states and tribes.	States will have greater flexibility to close unenforceable cases and redirect resources to more productive efforts. States will also have a process by which cases can be closed and transferred to a tribal child support program.
45 CFR §§302, 303, 308	Strengthen medical support in the child support program	ACF/OCSE	OCSE has a statutory responsibility to secure private or public health care coverage for each of the children in its caseload and to enforce court orders that require parents to obtain health care coverage. Previously, OCSE provided guidance to states providing them the option to define medical support to include private health insurance as well as Medicaid, CHIP, and other state coverage plans; however, to provide states with greater flexibility OCSE is revising the regulations, providing state child support agencies with the flexibility to pursue options such as enhancing collaboration with Medicaid and CHIP (OCSE-AT-10-10).	Medical support requirements will be reconciled with the health insurance reform legislation, and will substantially improve children's health care coverage and reinforce parents' shared responsibility for their children's coverage.
45 CFR Part 303	Efficiency in child support	ACF/OCSE	OCSE is drafting an NPRM which discontinues the mandate for States to notify other States involved in enforcing a support order when they submit an interstate case for offset. States referring past-due support for offset will notify any such other State involved in enforcing the debt only when they receive the offset amount from the United States Treasury States.	States will not be inundated with unnecessary information and will ultimately save both time and resources

45 CFR Parts 301, 302, 303, 304, 305, 307	Efficiency in child support	ACF/OCSE	OCSE is drafting an NPRM which improves document management, by allowing states to submit and accept information electronically, maintain electronic records, and accept electronic signatures.	OCSE, States, and others will have the flexibility to use cost-saving and efficient technologies, such as email or electronic document storage, wherever possible.
45 CFR §400.211(a)(5)	Methodology to be used to determine time-eligibility of refugees	ACF/ORR	Modification to the current provision that, for purposes of determining the time-eligibility period, States' most current reported administrative costs are both inflated by the CPI and adjusted by changes in program participation. The adjustment by changes in participation has not proved useful, over the 20 years that this methodology has been implemented, in projecting administrative costs. HHS will consider options to produce more accurate estimates of State administrative costs.	Changes will streamline and produce more accurate estimates of administrative costs.
Enhancing Research				
42 CFR 52h	Scientific Peer Review of Research Grant Applications and Research and Development Contract Projects	NIH	This regulation is already followed by other DHHS sister entities, so modifying and streamlining this rule could lessen regulatory burden and provide greater flexibility across the Department. Additionally, there appear to be opportunities for reducing administrative burdens. For example, revising definitions of conflicts of interest for peer reviewers could provide flexibility in constituting review panels and lessen administrative burden. Revising review criteria could provide greater flexibility in evaluating applications and make them applicable to other types of applications in addition to those for research projects. This is important given NIH's development of new types of initiatives in response to the changing nature of science for which the criteria specified in the current regulations are not optimal. Revising the regulations to allow for a pre-screening process could reduce the toll on the system.	We expect that regulatory review of the peer regulations could result in a unified set of peer review regulations for all HHS agencies that provides greater flexibility and reflects reduced regulatory and administrative burdens.
45 CFR 164.508	HIPAA Privacy Rule Authorization Requirements for Research	OCR	Streamline the HIPAA research authorization process and harmonize with the Common Rule's informed consent requirements	Will provide increased flexibility for researchers, reduce paperwork and burden, and harmonize with other research rules

45 CFR part 46, 160, 164 and 21 CFR 50 and 56	Protection of Human Subjects in Research (the Common Rule)	HHS with OSTP	The Advance Notice of Proposed Rulemaking seeks public comment related to the ethics, safety, and oversight of human research. Revisions to the Common Rule might a enable Institutional Review Boards (IRBs) to better focus their resources on review of research protocols that pose greater than minimal risks to subjects; improve the mechanism for collecting information to evaluate the effectiveness of the research oversight system in protecting human subjects; and facilitate research by reducing unnecessary burdens on institutions and investigators.	Better protection of human subjects who are involved in research, while facilitating, valuable research, and reducing burden, delay, and ambiguity for investigators and research subjects.

A.3 Agency-Specific Initiatives

CFR Cite	Reference	Agency	Purpose	Impact
FDA Medical Products				
21 CFR 803	Electronic Medical Device Reporting	FDA/CDRH	Would convert adverse events reporting of medical devices to a paperless system.	Would allow paperless reporting of adverse events
21 CFR	Down-classifications of Medical Devices (various)	FDA/CDRH	Review classifications of medical devices to determine if down-classification (i.e., move to a classification with less stringent requirements) is appropriate.	Regulate based on risks and reduce regulatory burden.
21 CFR 814	Revision of Device Premarket Approval Regulations (21 CFR 814.39); Special PMA Supplement Changes Being Effected	FDA/CDRH	Remove duplicative requirements	Streamline and clarify regulatory requirements.
21 CFR 882	Revise 21 CFR 882.5975 referencing device classification for dura mater, now regulated as an HCT/P	FDA/CDRH	Clarify classification of dura mater.	Clarification of regulatory status
21 CFR 351 21 CFR 360 21 CFR 371	General Hospital and Personal Use Devices; Issuance of Draft Special Controls for Infusion Pumps	FDA/CDRH	Based on an analysis of death and serious injury reports submitted to FDA, the agency is establishing special controls to provide reasonable assurance of safety and effectiveness of these devices.	Increased safety for patients.
21 CFR 801	Use of Symbols in Device Labeling	FDA/CDRH	Allow validated symbols in certain device labeling without the need for accompanying English text.	Reduce burden of labeling requirements by permitting harmonization with labeling for international markets
21 CFR 10 21 CFR 314 21 CRF 600 21 CFR 601 21 CFR 606	Postmarketing Safety Reporting Requirements for Human Drugs and Biological Products	FDA/CDER	FDA is revising certain definitions and reporting requirements based on recommendations of the ICH.	Revise reporting requirements and times to enhance the quality of safety reports received by FDA.
21 CFR 201 21 CFR 606	Bar Code Rule for Drugs	FDA/CDER & CBER	FDA is conducting a retrospective economic review of an economically significant regulation.	Assess costs and benefits to determine if rule should be modified to take into account changes in technology that have occurred since the rule went into effect.

21 CFR 210 21 CFR 211	Amendment to CGMP regulations for Finished Pharmaceuticals (Pharmaceutical CGMP for the 21st Century--Phase 2)	FDA/CDER	FDA is revising its CGMP regulations to accommodate advances in technology and to harmonize with the other International standards.	Flexibility and harmonization for pharmaceutical industry.
21 CFR 210 21 CFR 211	Amendment to CGMP regulations—Components	FDA/CDER	FDA is revising its CGMP regulations to address control of drug components.	Provide greater assurances of safety and quality and address some of the challenges of globalization of drug manufacturing.
21 CFR 314	Implementation of 505(q) – Amendment To Citizen Petitions, Petitions for Stay of Action and Submissions of Documents to Dockets	FDA/CDER	FDA is revising its existing regulations to implement provisions of the FDA Amendment Act.	Clarify certifications needed when filing petitions related to generic drug applications.
FDA Foods				
21 CFR 101	Food Labeling (Nutrition Initiative)	FDA/CFSAN	Revising and updating food labeling regulations to make nutrition information on packaged food label more useful to consumers.	Improving nutrition information will help consumers make better dietary choices.
21 CFR 110	Preventive Controls (Modernization of Current Food Good Manufacturing Practice Regulations)	FDA/CFSAN	In recognition that existing food GMP rules are inadequate, the Food Safety Modernization Act requires FDA to establish preventive controls for food facilities.	Reduced illness and death from food-borne illness.
CMS Conditions of Participation				
42 CFR Part 484	Home Health Agency CoPs Proposed Rule	CMS	Remove unnecessary prescriptive and burdensome requirements to reflect current practice and streamline operations.	Increase the amount of time clinicians can spend with patients and lessen time on paperwork.
42 CFR Part 482	Hospital CoPs Proposed Rule	CMS	Remove or revise multiple requirements that are inconsistent with other requirements or impose unnecessary burdens to increase flexibility.	Target to publish the proposed rule is September. Estimated net savings to hospitals could reach at least $600 million annually; $3 billion over 5 years.
42 CFR 405	Proposed Rule for Non-Hospital Facilities on Provisions to Promote Program Efficiency, Transparency, and Burden Reduction	CMS	Revise or eliminate provisions affecting non-hospital providers that are unnecessary, obsolete, or excessively burdensome.	Target for publication is September 2011. Improved access to care, increased flexibility, better quality and lower costs. CMS estimates the net savings to End Stage Renal Disease facilities, which will be affected most by these changes, could approach $200 million in the aggregate.
CMS Review of Appeals process and ALJ provisions				
42 CFR 405.720 and 722	Reconsiderations and Appeals Under Medicare Part A; Hearing; right to hearing.	CMS/OS-OMHA	Clarify and streamline appeals procedures.	Eliminate confusion and unnecessary duplication.
42 CFR 405.855	Appeals Under the Medicare Part B Program; ALJ hearing	CMS/OS-OMHA	Clarify and streamline appeals procedures.	Eliminate confusion and unnecessary duplication.

42 CFR 422 and 423	Contract Year 2012 Part C & D Final Rule	CMS/OS-OMHA	Translating the marketing materials for plan sponsors will result in significant savings to plan sponsors. CMS estimates per contract savings to be $15,200 for the first year of translation and $750 for annual updates for each of 305 sponsor contracts. CMS is investigating translating other Part C and D materials into other languages, so that plans need not undertake the translation themselves.	CMS estimates that net savings to plan sponsors could be as high as $4.6 million for 2012 and $230,000 for subsequent years.
42 CFR Part 498	Appeals Procedures for Determinations that Affect Participation in the Medicare Program and for Determinations that Affect the Participation of ICFs/MRs and Certain NFs in the Medicaid Program	DAB	Remove references to determinations by OIG because superseded by 42 CFR Part 1005	Eliminate confusion
42 CFR 430.2; 42 CFR 457.230; 45 CFR 1355.30(c)	Other applicable Federal regulations; FFP for State ADP expenditures; Other applicable regulations.	DAB	Remove outdated references to 45 CFR Part 74 to make regulations consistent with 2003 changes. Public assistance grants to states are now subject to 45 CFR Part 92. *See* 68 Fed. Reg. 52844 (Sep. 9, 2003).	Avoid disputes about what requirements apply
42 CFR Part 498.83(d)	Departmental Appeals Board action on request for review.	DAB	Remove outdated reference to Public Health Service and revise to state that "review will be conducted by a panel of at least *three* members of the Board, designated by the Chair or Deputy Chair," as intended.	Avoid confusion and possible procedural challenge
Various provisions under Titles 42 and 45 of CFR (e.g., 42 CFR 457.206©)	Administrative appeals under SCHIP.	DAB	Remove outdated references to "Departmental Grant Appeals Board" and replace with "Departmental Appeals Board"	Eliminate confusion
42 CFR Part, 488 Subpart C	Survey Forms and Procedures	DAB	Superseded by 42 CFR Part 488, Subpart E	Eliminate confusion

A.4 Other Reviews Consistent with 13563

CFR Cite	Reference	Agency	Purpose	Impact
Reconsideration of Need for Final Rule consistent with 13563				
RIN 0920-AA31	Possession, Use, and Transfers of Select Agents and Toxins (SARS-Cov and Chapare Virus)	CDC	Will merge with Biennial Review of List of Select Agents and Toxins (RIN 0920-AA34).	More efficient rulemaking
RIN 0920-AA04	Amendments to Quality Assurance and Administrative Provision for Approval of Respiratory Protective Devices	CDC	Review of comments to the NPRM indicates that additional analysis is needed to assess the economic impact of its proposed rule. CDC plans to withdraw the proposed rule and consider possible alternative approaches	Existing regulations will enforce quality assurance and administrative provisions while it explores alternative approaches.
RIN 0920-AA36	Amendments To Establish Wildland Firefighting Protection Performance Requirements for Approval of Respiratory Protective Devices	CDC	Respiratory Protection requirements were established in a national consensus standard, NFPA 1984, published March 2011. This NFPA standard requires NIOSH certification for respirators fulfilling the requirements of the standard.	NIOSH is considering the possibility of not publishing this Final Rule. Instead NIOSH will rely on the NFPA standard (which requires NIOSH certification) as it provides expected levels of respiratory protection.

Increasing Transparency consistent with 13563

42 CFR 422 and 423	Contract Year 2012 Part C & D Final Rule	CMS	CMS began annual rulemaking to promote transparency, enhance beneficiary protections, fine-tune policy, improve CMS oversight of its contracts, and eliminate duplicative and outdated regulations. Both the industry and the advocacy community have been supportive of annual rulemaking as a way of increasing transparency in CMS' policy development process. The industry wants the annual regulations published as early as possible in the year to allow maximum time to implement policy changes prior to the bid submission deadline for the following contract year (first Monday in June).	Increase transparency
42 CFR Part 441	Home and Community Based Services Waivers	CMS	The provision is unnecessary or obsolete because it hinders State Medicaid programs from designing waivers based on functional need and prevents States from consolidating waiver services to multiple target groups. The consolidation of waivers reduces the administrative costs to States for management and oversight, and potentially offers a better tool for State allocation of scarce resources across multiple target populations.	Reduced administrative burdens and costs to states and better tools for states to use in administering the program.
45 CFR 60 and 61	Merger of the National Practitioner Data Bank for Physicians and Other Health Care Practitioners with the Healthcare Integrity and Protection Data Bank (HIPDB) for Final Adverse Information on Health Care Practitioners, Providers and Suppliers	OIG/HRSA	Section 6403 of Affordable Care Act merges the HIPDB into the National Practitioner Data Bank (NPDB), thereby eliminating the need for 45 CFR 61	Merging the Data Banks reduces burdens on users by eliminating the need for users to follow two different regulations and pay two separate fees to obtain information; Eliminates OIG and DOJ oversight of the HIPDB.

Other Activities consistent with 13563

42 CFR Part 412	Inpatient Rehabilitation Facility Prospective Payment System Final Rule	CMS	Removes outdated and unnecessary requirements, including change in ownership regulations and mergers and acquisitions. This action will help CMS better meet changing patterns of demand for IRF services. CMS gets numerous questions from providers regarding the interpretation of these requirements because they are difficult to interpret and are repetitive. CMS also believes that these requirements are outdated and are no longer necessary.	Published July 29, 2011. Expected to reduce burden and increase flexibility.
21 CFR 606 21 CFR 630	General Requirements for Blood, Blood Components, and Blood Derivatives; Donor Notification	FDA/CBER	FDA is reviewing this regulation as required by sec. 610 (c) of the Regulatory Flexibility Act.	Fulfill requirements of Regulatory Flexibility Act.
21 CFR 203 21 CFR 205	Prescription Drug Marketing Act of 1987; Prescription Drug Amendments of 1992; Policies, Requirements and Administrative Procedures	FDA/CDER	FDA is reviewing this regulation as required by sec. 610 (c) of the Regulatory Flexibility Act.	Fulfill requirements of Regulatory Flexibility Act.
21 CFR 1002 21 CFR 1010 21 CFR 1040	Laser Products; Amendment to Performance Standards	FDA/CDRH	Amending the performance standards for laser products to achieve closer harmonization with the International Electrotechnical Commission (IEC)	Would harmonize more closely with the IEC and reflect current advances in science.

			standards.	
21 CFR 203 21 CFR 205	Prescription Drug Marketing Act of 1987; Prescription Drug Amendments of 1992; Policies, Requirements and Administrative Procedures	FDA/CDER	FDA is reviewing this regulation as required by sec. 610 (c) of the Regulatory Flexibility Act.	Fulfill requirements of Regulatory Flexibility Act.
45 CFR 61	Healthcare Integrity and Protection Data Bank (HIPDB) for Final Adverse Information on Health Care Practitioners, Providers and Suppliers	HRSA	Section 6403 of Affordable Care Act merges the HIPDB into the National Practitioner Data Bank (NPDB), thereby eliminating the need for 45 CFR 61	Cost savings for organizations and practitioners who have the authority to obtain HIPDB; Time saving for reporters and queries of the Data Bank information; Eliminates OIG and DOJ administration of the HIPDB.
31 CFR Part 33 and 45 CFR Part 155	State Innovation Waivers under Section 1332 of the Affordable Care Act	CMS (with Treasury)	HHS and Treasury jointly-issued a proposed rule allowing States to apply for a waiver of certain statutory requirements of the Affordable Care Act. The waivers will be known as State Innovation Waivers and would promote state flexibility in designing "health care solutions that work best for them." This effort is consistent with E.O. 13563.	Increase flexibility for States.
Other CMS Rules under Review				
42 CFR Part 416	Ambulatory Surgical Centers (ASC) Conditions for Coverage: Same-Day Services Final Rule	CMS	Reduce burden on ASCs and improve timeliness in access to care by allowing patients' rights information to be given on the day of the services.	$50 million in savings annually--Savings in patient time of $35 million; $17.5 million in savings for providers.
42 CFR Part 418	Hospice Wage Index PPS Final Rule	CMS	The current requirement states that the physician who conducts the face-to-face visit with a Medicare hospice patient prior to recertification must be the same physician who completes the recertification. This may risk access to care for patients in areas of physician shortages, and is burdensome for hospices to implement, given the difficulty some hospices have in obtaining physician resources.	Published on July 29, 2011. Expected to increase flexibility and reduce burdens on hospice services and physicians.
42 CFR Part 416	Physician Fee Proposed Rule	CMS	Remove the new lab signature requirement that the physician sign orders for a clinical lab test. Reduces burden by eliminating unnecessary documentation. The physician, clinical laboratory, and nursing home community perceive the existing requirement to be a significant additional burden; and the clinical laboratory industry believes they will not be paid for many laboratory tests because they do not anticipate full compliance.	Published July 19, 2011. Expected to reduce burdens and increase flexibility.
42 CFR Part 440	Home Health Face-to-Face Requirement	CMS	Align this requirement for Medicaid with the existing requirement for Medicare that physicians document a face-to-face encounter with the Medicaid beneficiary within certain timeframes.	Published July 12, 2011. Expected to reduce unnecessary burdens of two different requirements. CMS's Office of the Actuary estimates that the net savings from this change will result in savings to

				Medicare of roughly $870 million over ten years.
Other FDA Rules under Review				
21 CFR 558	Veterinary Feed Directives	FDA/CVM	Improve efficiency of the process for veterinarians to issue feed directives.	Streamlined VFDs will assist veterinarians and medicated feed manufacturers.
21 CFR 514 21 CFR 510	New Animal Drugs—Records and Reports concerning experience with approved drugs and medicated feeds	FDA/CVM	Reviewing regulations to determine how to clarify, streamline, and harmonize.	Aligning with international standards and clarifying requirements will result in improved reporting by sponsors.
21 CFR 58	Good Laboratory Practice for Nonclinical Investigations	FDA/OC	Review standards for nonclinical investigations to determine how best to update them.	Update standards for nonclinical investigations.